

REMARKS

The Office Action mailed October 2, 2001 (hereinafter the Office Action), has been received and reviewed. Claims 36-55 are pending in this application. Claims 36-55 are rejected. Applicants respectfully request reconsideration of the application in light of the remarks set forth herein.

35 U.S.C. § 102 and 35 U.S.C. § 103 Rejections

Applicants herein respond to the Office Action mailed October 2, 2001 in the above-identified application. All of claims 36-55 stand rejected under 35 USC 102(b) or 103(a) as unpatentable over Gerstel et al. U.S. Patent No. 3,964,482. Claims 36-55 comprise "apparatus" claims 36-44 and "method" claims 45-55. The "apparatus" claims 36-44 are directed to an applicator used to apply a microprotrusion array to skin. Microprotrusion arrays are shown as element 2 in Figs. 3 and 5 of the present application. These arrays have a plurality of skin piercing microprotrusions which are adapted to pierce the outermost layer (ie., the stratum corneum layer) of the skin to a very shallow depth.

The applicator used to press the microprotrusion arrays against the skin in order to cause microprotrusion piercing is shown in Fig 12 of the present application. The applicator 112 has a head 115 with a curved impact surface 111 which is adapted to make contact with the skin distal side of the microprotrusion array. As is clearly shown in Fig. 12, the contact surface 111 has a curved, roughly cylindrical shape.

Independent "apparatus" claim 36 recites that the surface which engages the microprotrusion array has "a shape selected from the group consisting of convex, curved and cylindrical." Independent "method" claim 45 also recites that the applicator head has a surface having a shape "selected from the group consisting of convex, curved and cylindrical".

As mentioned above, all of the claims stand rejected over Gerstel et al., U.S. Patent No. 3,964,482. The disclosures of Gerstel et al. are distinguishable from the presently claimed subject matter in two important respects. First, Gerstel et al. discloses no applicator as that term is used in the present application. Gerstel et al. does disclose microprotrusion arrays having a plurality of skin piercing microprotrusions which are adapted to pierce the outermost layer of the skin to a very shallow depth in order to introduce a therapeutic agent therein. However, Gerstel et al. only describes applying these microprotrusion arrays by manually applied finger pressure. The Gerstel et al. arrays are pressed against the skin using pressure applied by the user's fingers. See for example column 12, line 61-64 and column 16, lines 11-14 and 29-31. Gerstel et al. disclose no apparatus other than the user's fingers for applying pressure to the microprotrusion arrays to cause the piercing.

Second, Gerstel et al., disclose no applicator or other structures having a convex, curved and/or cylindrical surface. Applicants have discovered that the use of a curved, convex or cylindrical surface on the applicator head results in approved microprotrusion penetration, particularly with very small (i.e., lengths of less than 300 μ m) microprotrusions. Thus, the presently claimed invention offers advantages not found in the Gerstel et al. teachings. Certainly, the Gerstel et al. patent contains no hint or disclosure of using an applicator of the type disclosed in Fig. 12 herein. Gerstel et al. do disclose a structure (i.e., a compartment) on the skin distal side of the array. The compartment has vertical walls 16, a flat base 14 and a flat top (no reference number is provided for the flat top shown in Gerstel's Figs. 1 and 2). The compartment is filled with a liquid or soft solid (e.g., gel) material 20. However, this structure is not an "applicator" as that term is used herein since it does not apply pressure to the microprotrusion array to cause skin piercing. Rather this structure having a flat or rectangular cross-section merely transmits the pressure applied by the user's fingers. At most, Gerstel et al. could be said to disclose an "applicator" having a flat (i.e., not curved) structure contacting the skin distal side of the microprotrusion array. Thus, Gerstel et al. does not anticipate nor render obvious the subject matter of claims 36-55.

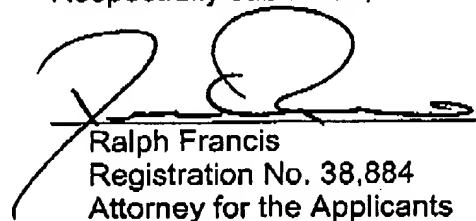
Please direct any questions to the undersigned attorney at (650) 564-2901.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

Dated: 1/29/04

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